DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs; Ractopamine

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of two new animal drug applications (NADAs) filed by Elanco Animal Health. One NADA provides for use of ractopamine and monensin Type A medicated articles to make dry and liquid two-way combination Type B and Type C medicated feeds for cattle fed in confinement for slaughter. The other NADA provides for use of ractopamine, monensin, and tylosin Type A medicated articles to make dry and liquid three-way combination Type B and Type C medicated feeds for cattle fed in confinement for slaughter.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Eric S. Dubbin, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0232, e-mail: *edubbin@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285, filed NADA 141–225 that provides for use of OPTAFLEXX (ractopamine hydrochloride) and RUMENSIN (monensin sodium) Type A medicated articles to make dry and liquid two-way combination Type B and Type C medicated feeds used for increased rate

of weight gain, improved feed efficiency, and increased carcass leanness; and for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* in cattle fed in confinement for slaughter during the last 28 to 42 days on feed. Elanco Animal Health also filed NADA 141–224 that provides for use of OPTAFLEXX, RUMENSIN, and TYLAN (tylosin phosphate) Type A medicated articles to make dry and liquid three-way combination Type B and Type C medicated feeds used for increased rate of weight gain, improved feed efficiency, and increased carcass leanness; for prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*; and for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces (Corynebacterium) pyogenes* in cattle fed in confinement for slaughter during the last 28 to 42 days on feed. The NADAs are approved as of January 27, 2004, and the regulations are amended in 21 CFR 558.355, 558.500, and 558.625 are to reflect the approvals. The basis of approval is discussed in the freedom of information summaries.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), summaries of safety and effectiveness data and information submitted to support approval of these applications may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(2) that these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

■ 2. Section 558.355 is amended by adding paragraph (f)(7)(iii) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(7) * * *

(iii) Ractopamine alone or with tylosin as in § 558.500.

3. Section 558.500 is amended in paragraph (d)(3) after ''7.5'' by adding ''or, if in combination with monensin and/or tylosin, at a pH of 4.5 to 6.0''; and by revising the table in paragraph (e)(2) to read as follows:

§ 558.500 Ractopamine.

* * * * *

(e) * * *

(2) *Cattle*—

Ractopame in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 8.2 to 24.6		Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency during the last 28 to 42 days on feed	Feed continuously as sole ration during the last 28 to 42 days on feed. Not for animals intended for breeding	000986
(ii) 8.2 to 24.6	Monensin 10 to 30	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(i) of this section; and for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*	As in paragraph (e)(2)(i) of this section; see § 558.355(d) of this chapter	000986
(iii) [Reserved]				
(iv) 8.2 to 24.6	Monensin 10 to 30, plus tylosin 8 to 10	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(i) of this section; for prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*; and for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces (Corynebacterium) pyogenes*	As in paragraph (e)(2)(i) of this section; see §§ 558.355(d) and 558.625(c) of this chapter	000986
(v) [Reserved]				
(vi) 9.8 to 24.6		Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness during the last 28 to 42 days on feed	Feed continuously as sole ration during the last 28 to 42 days on feed. Not for animals intended for breeding	000986
(vii) 9.8 to 24.6	Monensin 10 to 30	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(vi) of this section; and for prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*	As in paragraph (e)(2)(vi) of this section; see § 558.355(d) of this chapter	000986
(viii) [Reserved]				
(ix) 9.8 to 24.6	Monensin 10 to 30, plus tylosin 8 to 10	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(vi) of this section; for prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*; and for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces* (*Corynebacterium*) *pyogenes*	As in paragraph (e)(2)(vi) of this section; see paragraphs §§ 558.355(d) and 558.625(c) of this chapter	000986
(x) [Reserved]				

■ 4. Section 558.625 is amended by revising paragraph (f)(2)(vii) to read as follows:

§ 558.625 Tylosin.

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(f) * * *

(2) * * *

(vii) Ractopamine alone or with monensin as in § 558.500.

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Dated: March 3, 2004.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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